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PRINCIPAL INVESTIGATOR(S): LTC D. E. Casey Jones, MD
LTC Richard Sherman

CONTRACTING ORGANIZATION: Madigan Army Medical Center
Tacoma, Washington 98431-5000

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Casey Jones, LTC

Richard Sherman, LTC

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13. ABSTRACT

The literature and clinical experience indicate that the overwhelming incidence of pelvic area stress fractures is among women engaged in strenuous activities. Pulsing electromagnetic fields (PEMFs)have been shown to speed the healing of non-union fractures and we have used them successfully to treat stress fractures in the lower limbs. All women at Ft. Lewis who have the clinical symptom complex indicative of pelvic area stress fractures are being referred for bone scans. Thirty soldiers meeting the criteria have had bone scans but only four have been positive. Subjects with negative bone scans but meeting all other criteria are placed into the musculoskeletal pelvic pain group. Patients are stratified by presence or absence of a fracture and then randomized into actual PEMF and placebo PEMF groups and treated for one hour per day until they return to duty. Changes in the bone scan are used to determine differences between the fracture groups while differences in pain and return to duty are used to determine differences between the musculoskeletal groups. Results to date indicate that pelvic stress fractures are being misdiagnosed. If these results are confirmed, treatments for women showing this symptom complex may be changed as they receive treatments designed to ameliorate stress fractures.

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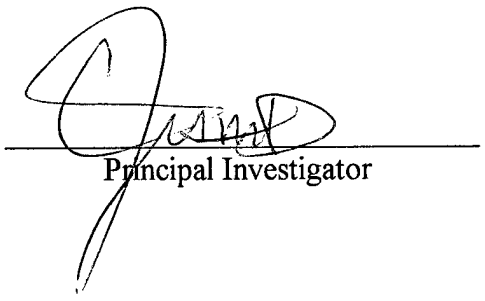


10 August, 1995

Principal Investigator

TABLE OF CONTENTS

1. INTRODUCTION:

a. **Objectives**:

1. To determine whether application of Pulsing Electromagnetic Fields (PEMFs) over the stress fracture site or the site of maximal musculoskeletal pain, used in conjunction with standard therapeutic approaches, (a) increases the rate of healing of the stress fractures as determined by changes in bone scans or reduces pain while increasing range of motion among subjects with musculoskeletal pain and (b) reduces the time to return to full duty in relation to those receiving the standard treatments and placebo PEMFs.

2. To determine the percentage of female soldiers who show the complex of symptoms indicative of pelvic area stress fractures who have conformation of these fractures by bone scan.

b. **Hypotheses**:

1. That application of PEMFs over the stress fracture site, used in conjunction with standard therapeutic approaches, (a) increases the rate of healing of pelvic stress fractures and (b) reduces the time to return to full duty in relation to those receiving the standard treatments and placebo PEMFs.

2. That application of PEMFs over the site of maximum pain among female soldiers with musculoskeletal pelvic pain, used in conjunction with standard therapeutic approaches, (a) increases range of motion, (b) decreases pressure induced pain, and (c) reduces the time to return to full duty in relation to those receiving the standard treatments and placebo PEMFs.

3. That very few of the women who meet the current clinical criteria for pelvic area stress fractures actually have this problem.

c. **Medical and military applications**: Reduction in the number of days of training and work time lost before return to full duty and an decrease in the number of female soldiers who have to be boarded out due to pelvic stress fractures and musculoskeletal pelvic pain are important to the system. Our pilot data indicate that a minimum of a ten day decrease in the time to return to full duty is likely to accrue. A large minority patients require many months of inactivity to heal and, even then, never return to full levels of activity. It is possible that this treatment will help these relatively slow healers return to full duty more quickly.

d. **Status**:

1. Pelvic stress fractures: Meurman (1980) found that about six percent of stress fractures (39 out of 600) occurring among Finnish military recruits were in the pubic arch. It took an average of thirty days (range of 1 - 83) to make an accurate diagnosis of their problem. However he reports that Morris and Blickenstaff (1967) found only four cases out of 700 stress fractures among soldiers. Matheson et al (1987) found that 1.6 percent of their series of 320 stress fractures occurring among athletes were in the pelvic area. They reported that the average time between occurrence of symptoms and diagnosis was 13.4 weeks (range of 1 to 78) with the average time to recovery being 12.8 weeks. Meurman (1980) states that pain was most often reported in the sacral, inguinal, perineal, or gluteal regions, became worse with exercise, and improved with rest.

Moran (1988) discussed pubic stress fractures during the later stages of pregnancy and related their occurrence to increased physical activity among pregnant women. Thorne and Datz (1986) reviewed information on pelvic stress fractures in females runners and found that their usual complaint was groin pain. Both Matheson et al (1987) and Pavlov et al (1982) found that the preponderance of pelvic area stress fractures occurred among very active young females (a ratio of 9 to 2).

2. Use of pulsing electromagnetic fields to speed recovery: This technology has been in use since the 1950s. It has recently been used very successfully by the Army in a study on treatment of grade I and II ankle sprains (Pennington et al 1993). Pennington's article reviews the safety of the technique and its usefulness for speeding recovery and reducing swelling. Kaplan & Weinstock

(1968) performed a double blind study with 100 foot surgery patients and found that pulsed fields significantly reduced swelling and pain. The technique has been successfully used to prevent initial development of edema and pain in burn patients (Ionescu et al 1982). It has also been successfully used to reduce swelling and control pain among 250 patients with non-operative hand injuries participating in a controlled study (Barclay et al 1983). Pulsed fields also sped the healing of donor site wounds in patients in a double blind trial (Goldin et al 1981).

3. Use of pulsing magnetic fields for helping delayed union and nonunion fractures heal: Uncontrolled clinical trials have reported the use of low frequency pulsing electromagnetic fields to speed and promote the healing of delayed union and nonunion fractures in clinical trials since the 1970s (e.g. Sharrard 1989). At least 14 of the papers report the technique's use for these problems in the tibia. Taken together, they represent trials with 1,275 patients of whom an average of 81% healed after a significant pause in progress (Technology Evaluation, 1989). More recently, double blind studies indicating the technique's effectiveness on a wide variety of bones have been published. For example, Sharrard (1989) performed a double blind study of 45 fractures of the tibial shaft and in which 20 received active coils and 25 received dummy units. Orthopedic examination indicated that nine of the subjects in the active group showed healing relative to three in the control group. Objective radiological evaluation indicated union of five fractures and progress toward union in an other five fracture in the active group compared with union in one fracture and progress toward union in one fracture in the control group. Thus, the technique has been shown to be effective in helping nonunion and delayed union fractures of the tibia.

We are only aware of one study in which magnetic fields were used with delayed union stress fractures. The study was done with fractures of the tibia. The authors found that of 8 subjects with confirmed delayed unions, 7 healed with a combination of rest and magnetic fields.

The mechanisms through which PEMFs produce their effects are not known. However, it has been demonstrated that they do not significantly heat exposed tissues so they do not work by heating the effected areas. It has also been demonstrated that PEMFs cause a significant increase in blood flow to exposed tissues. They also have an effect on movement of charged ions in bone and across membranes so may produce their effect on bone healing by directly increasing calcium deposition and/or increasing blood flow in the bones and surrounding tissues. This work has been reviewed in O'Connor et al's book on Emerging Electromagnetic Medicine.

The instruments used to produce and apply the field generally consist of a charger, a combined control and generator unit, and a field coil. The unit is mounted on a rolling cart and the extendable head is positioned over the patient. A typical unit is illustrated in Figure One on the next page.

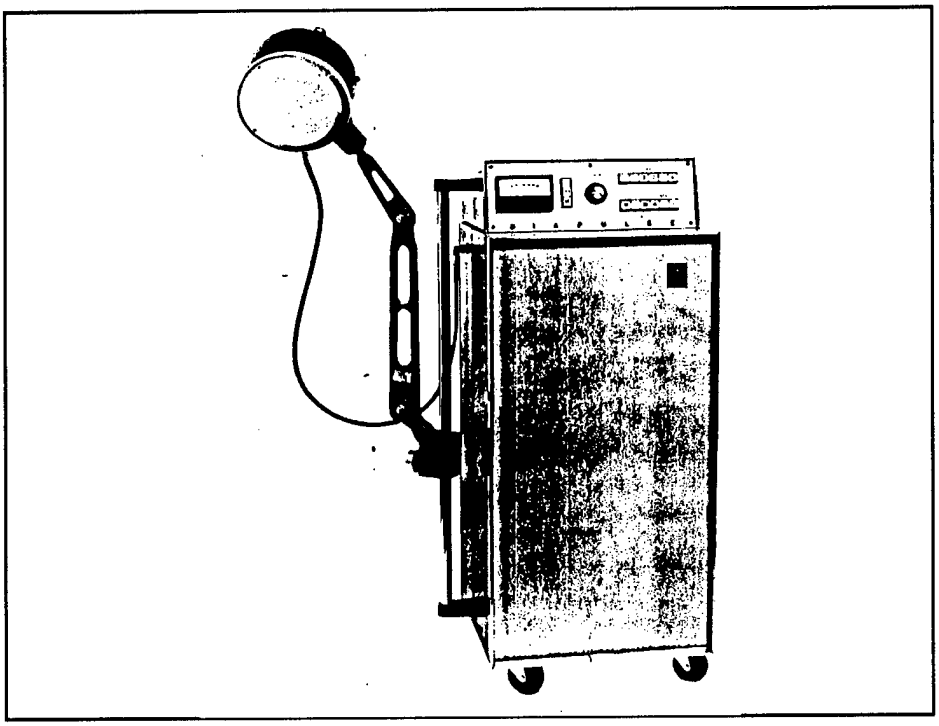
4. Effect of PEMFs on stress fractures among Army trainees: This team conducted a double blind, placebo controlled pilot study in which the time to return to work, number of hours per day able to stand, and pain patterns were recorded from people with lower limb and metatarsal stress fractures related to Army basic training. Eleven patients with radiologically confirmed tibial and metatarsal stress fractures who received the standard treatment in addition to being exposed to PEMFs five times per week for one hour per day were compared with thirteen similar patients who received the standard treatment and placebo PEMFs. In order to be returned to full activity, participants had to demonstrate: the ability to run for two miles without pain or difficulty, no pain on palpation of the fracture site. no vibratory sensitivity. no edema or erythema at the fracture site, and no pain with weight bearing with increased activity. All had positive X-rays prior to treatment and negative X-rays upon return to full activity. All pre and post X-rays were evaluated (blindly) by the Chief of Orthopedics. The subjects exposed to PEMFs returned to their normal levels of activity without pain in an average of 31.7 days (Standard Deviation = 6.8) while the placebo subjects returned in 38.2 (12.5) days. An independent "t" test between the PEMF and placebo groups did not indicate that the mean difference of 6.5 days was statistically significant ($t = 1.39$ with 19 DF, one tail probability = 0.09). However, a week of time off work is important.

5. Use of pulsed magnetic fields to speed healing of normally healing fractures: We are not aware of any studies showing the techniques' usefulness (or lack there of) for speeding the healing of normally healing fractures. However, we are aware that it has been tried clinically and has a mixed reputation for success. The problem is that fractures heal at very different rates due to many known and probably more unknown and idiopathic factors so a very large group of people of similar ages and physical conditions having similar fractures of similar severities who would all get the same treatment would have to be gathered together in one place at about one time in order to evaluate the technique's effect. An other complicating set of factors involves the interference of fracture treatment methodologies such as plates, screws, and etc. with operation of the fields and the fact that each appliance has to be placed differently depending on the needs of the patient. Differences in movement around the fracture also complicate the situation.

Figure One

TYPICAL PULSING ELECTROMAGNETIC FIELD GENERATOR*

The unit is about one meter tall and is designed so that the heat can be positioned over a bed or chair. The head is placed within a few millimeters of the site to be exposed. The field extends about 12 cm from the head.



*Diapulse generator model D103
photo courtesy of Diapulse Corporation of America
321 East Shore Rd
Great Neck, NY 11023-2420

2. BODY (METHODS):

a. **Overview of design**: The experimental design will be the same as the one used in the pilot. Women identified as having the symptom complex indicative of pelvic area musculoskeletal pain will be given a bone scan to determine whether they have a pelvic area stress fracture. Subjects will be stratified depending on whether or not they have radiologically diagnosed pelvic area stress fractures and will receive one hour of PEMF or placebo PEMF therapy five days per week in addition to the standard treatment (sharply reduced activity and minimized walking) from the time the diagnosis is made until return to full duty. Subjects will be randomly assigned to groups and evaluated as described below.

The device was described in the status section and illustrated in Figure One. The patient will lay on an exam table with the head of the PEMF generator positioned several millimeters above the stress fracture site. The patient will be exposed to the fields for 15 minutes while on their backs and an additional 15 minutes while on their fronts. This is necessary because the field can not penetrate the entire width of the body. Thus, each subject will have a total of 30 exposure to

the field every day until they return to duty. The machine makes the same humming sound regardless of whether or not it is generating a field and subjects can not feel the field. Thus, subjects should not be aware of whether they are in the exposure or placebo group. The technician who turns on the device will know which group the subject is in so the machine can be set for either actual or placebo functioning but the technician and physicians doing the evaluations will have no idea which group the patients are in.

b. **Subjects**:

(1) Inclusion and exclusion criteria: Subjects must be between the ages of 18 and 45. They must be healthy other than having the symptom complex indicative of a pelvic area musculoskeletal pain or stress fracture. The fracture must be confirmed by bone scan for subjects to enter the fracture group.

(2) Assignment to groups: Random by picking a numbered card sealed in an envelope from a basket. The study technician stratifies and then randomizes the subjects and provides the treatment so nobody who evaluates the patients knows which group they are in.

(3) Number of subjects: A power analysis using Cohen's formulae (Cohen 1988) of the pilot results reported above shows that 33 subjects will be needed in each group assuming (a) that we predict the PEMF group will do better (one-tailed test), (b) an 80% chance of finding a difference between the two groups at a 0.05 level of significance, and (c) the pelvic stress fracture subjects do at least as well as the tibial and metatarsal stress fracture patients did in the pilot. Thus, a total of about 66 subjects will be required. If the dropout rate is the same as in the pilot, an additional ten to twenty subjects will have to be started so a total of as many as 80 subjects will participate. A power analysis will be performed after the first ten subjects participate in each group to give a firmer idea of how many will be required for this study.

(4) Source of subjects: Subjects will be drawn from the pool of patients referred to Orthopedic Surgery and OB-GYN at Madigan AMC. It is anticipated that sufficient subjects will be available because of the great number of physically active young female soldiers at Ft. Lewis who report appropriate symptoms to OB-GYN. As thirty appropriate subjects have been identified to date, there is little doubt that sufficient numbers will be available to complete the study.

(5) Subject identification: Each subject's data will be given a sequential group code when stored outside of her medical record. Clinical records will be kept in the usual way. Additional information recorded for study purposes will be kept in a locked file until patient identification is removed and coding is substituted.

(6) Risks and benefits: Maximum benefit to minimum risk.

(7) Precautions and corrective actions: If a patient has an unanticipated, negative reaction to the stimulator, the person will stop using it but the results will be included in the analysis.

c. **Project Medications and Devices**: No medications are involved. The PEMF stimulator was described above and has been approved by the FDA.

d. **Evaluations**: Subjects will be questioned prior to treatment every day about use of medications for pain, swelling, etc.; and pain. Pain will be assessed before each session. Subjects will rate their pain on a scale of zero to ten using a visual analog scale. Differences in amount of pain medications required will also be assessed. The bone scan and the clinical examinations would be given regardless of participation in the study so are not part of it. However, the clinical data and results of the bone scans are recorded. For patients with stress fractures, progress will be determined by changes in bone scans and duty status. Patients with musculoskeletal pelvic area pain will be evaluated by time to return to full duty, changes in amount of pressure over the most painful area required to produce discomfort and videothermograms of muscle inflammation.

This a double blind study because the subject will not know whether the device is working and the people evaluating the data and performing the measurements will not know which group the subjects are in.

When subjects complete participation in the study, they will be asked whether they thought they were in the placebo or the active treatment group. This will be done to insure that the outcome was not affected by most of the subjects receiving the placebo being aware of and, thus, destroying the value of the placebo group.

e. **Data:**

(1) The data to be collected are stated above in the evaluation section.

(2) Changes in the amount of pain will be analyzed using a non-parametric two way repeated measures analysis of variance (a time series analysis) in which the repeated measure will be the subject's pain at each evaluation and the independent measure will be the active vs. placebo group. Differences in amount of initial pain and then subsequent decrease as well as changes in pressure sensitivity will be determined using a non-parametric correlation with the lines split at the point of maximum pain. Changes in bone scans and time to return to duty will be analyzed using Mann-Whitney "U" tests.

f. **Changes in the protocol since its inception and progress to date:**

(1) Clarification of location of stress fractures: Pelvic stress fractures are in the areas of (a) the femoral neck (b) the sacrum, (c) the hip, and (d) the other pelvic bones.

(2) Change in study emphasis:

(a) The study initially projected that 80 active duty females with pelvic area stress fractures could be identified in one year for treatment with either pulsing electromagnetic fields or placebo. This was based on the estimated rate of clinical diagnoses of pelvic area stress fractures found both in the literature and our clinical experience. The referral rate of women with the appropriate cluster of symptoms has been at the predicted level. Thirty active duty women have been identified to date as having pelvic stress fractures by the usual, accepted, clinical criteria. Although we expected the condition to be overdiagnosed, we were very surprised to find that only four were confirmed scintigraphically. Changes in the scintigraphic findings are the crucial outcome measure as they are the only objective means of determining whether the treatment technique is actually altering the fracture (as opposed to altering pain by changing some other problem) so we can not include subjects who do not have radiological evidence of a stress fracture in a stress fracture treatment study.

(b) The female soldiers who met the clinical criteria for pelvic area stress fractures but do not have positive bone scans also do not have detectable OB-GYN, bone or other problems diagnosable by standard techniques. They do, however meet the criteria for musculoskeletal pelvic pain. We do not have any objective methods for diagnosing this condition but the women referred for this study are all of the women we are aware of at Ft. Lewis who would receive this diagnosis. Other studies have shown PEMFs to be effective in the treatment of other musculoskeletal pain problems so this is a rational treatment given that all non-surgical treatments have failed. Thus, we are changing our entrance criteria to:

(1) Include women diagnosed as having musculoskeletal pelvic pain (they meet the clinical, but not scintigraphic, criteria for a pelvic stress fracture).

(2) Change the emphasis of the study to include determining the proportion of women diagnosed with pelvic stress fractures relative to musculoskeletal pelvic pain

(3) Widen the entrance criteria so sufficient women with scintigraphic evidence of stress fractures can participate to continue the stress fracture arm of the study. We have decided to make these changes because the information will make an immediate impact on clinical practice and, especially, on the way active duty women are evaluated and treated.

(c) The study manager is concentrating on identifying all women with the clinical diagnoses and collecting the appropriate clinical information upon which the diagnosis was based. This is especially important because almost all of these soldiers are on temporary profile. These women have not been consented to participate in the study at this time as only a summary of existent medical data (the clinical findings and the radiological results) has been recorded and the intention was to discard the individual's names once the data were gathered. All of these women will be recontacted and asked to participate in the treatment arm of the study. Any who agree will be asked to consent to participation at that time.

(d) The study assistant will randomize the subjects after stratifying them into those with and without scintigraphic evidence of stress fractures and will continue to perform the real or placebo treatments.

(3) Status of consent of subjects into the study: Both of the subjects who began participation in the study were entered by a different method than the one detailed in the protocol. The first had already begun clinical treatment when asked to participate in the study when the entrance criteria were widened so was put into the active treatment group automatically. She was consented more so that she would be aware that she was receiving an experimental treatment than to actually include her data in the study. She was considered an initial "practice" subject by the staff. The second subject was randomized by the study coordinator rather than by the study technician at the decision of the project director. Thus, the study coordinator, but not the subject, knew which group she was in. This prevented double blinding but was not considered important at the time as the study coordinator has no influence on how the bone scans are interpreted. However, as the coordinator does have access to the records, so, on reconsideration, it was decided to return to the original policy of having the technician do the randomizing. This subject dropped out of the study so discussion about whether her data could be used is irrelevant.

(4) Determination of incidence of musculoskeletal pelvic pain: One of the studies being conducted by Surgical Research Service is asking all of the female soldiers in a variety of field units at Ft. Lewis to check off which pain problems they have as part of an anonymous impact questionnaire. One of the items which can be checked off is significant pelvic area pain associated with activity. The study coordination will compile this data so we can get an idea of the overall incidence of pelvic area pain related to exercise among female soldiers. Soldiers answering the questionnaire have the option to identify themselves if they want a clinical evaluation of their problems so it is very likely that most of the women with significant problems who should be entered into the study's data base will be identified.

(5) Availability of subjects for the study:
(a) Non-active duty women eligible for care at Madigan are now being included in the study because only four active duty women with radiologically confirmed stress fractures have been identified to date while sufficient non-active duty women are likely to be identified to differentiate between the placebo and active treatment groups.

(b) The thirty subjects identified as having musculoskeletal pelvic pain will be included in the treatment arm of the study as soon as we get permission from Madigan's IRB to do so. We anticipate identifying an additional thirty patients from the study described above in the next two months so sufficient patients will be available to complete the study as projected.

(6) Availability of equipment to complete the study: An additional pulsing electromagnetic field generator has been ordered so that all of the subjects will be able to be scheduled.

(7) Change in outcome measures for subjects diagnoses as having stress fractures: The initial study design included performing videothermographic, range of motion, and pain sensitivity to pressure measurements as methods for tracking changes in the problem. All of these have been shown to be too non-specific to stress fractures to be useful outcome measures. This was partially determined by analysis of the data from two studies which were being conducted by Surgical Research Service personnel during the time this protocol was initiated. **Subjects with musculoskeletal pelvic pain will still have these measures made as they are recognized correlates of changes in musculoskeletal pain syndromes.**

(8) The title of the study needs to be changed to: Use of pulsing electromagnetic fields for the treatment of pelvic stress fractures **and musculoskeletal pelvic pain** among female soldiers.

(9) The consent form has been changed to reflect the change in (a) project title, (b) diagnoses included, and (c) population. A copy of the revised form is enclosed.

3. CONCLUSIONS: Female soldiers currently being diagnosed as having pelvic stress fractures usually do not have stress fractures which can be confirmed by bone scan. Rather, they have musculoskeletal pelvic pain which is likely to require different treatments. This is based on only

four of thirty patients meeting the clinical criteria having positive bone scans.

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